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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/098,644	03/15/2002	Susan A. Gregory	C2916/4 (PHA 4151.7)	-7986

321 7590 02/24/2004

SENNIGER POWERS LEAVITT AND ROEDEL  
ONE METROPOLITAN SQUARE  
16TH FLOOR  
ST LOUIS, MO 63102

EXAMINER

SEAMAN, D MARGARET M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

### Office Action Summary

**Application No.**

10/098,644

**Applicant(s)**

GREGORY ET AL.

**Examiner**

D. Margaret Seaman

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-20 and 22-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-20 and 22-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 9-20 and 22-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is not seen where the instant specification provides the written description of the claimed invention of a composition of a COX-2 inhibitor, a 5-lipoxygenase inhibitor and an immunosuppressive drug. The specification does not disclose nor provide any suggestion as to how such a compound that is either a COX-2 inhibitor, a 5-lipoxygenase inhibitor or an immunosuppressive drug could be made or otherwise obtained other than by a trial-and-error research. The instant composition is not claimed such that one skilled in the art can recognize what is claimed. The instant specification does not disclose the structure or physical properties of all the drugs that are required to practice the instant composition (see claim 9). Also, the structures of such compounds cannot be deduced from any known structure-function correlation. The instant specification discloses a hoped-for function

(composition) for as-yet-to-be-discovered compounds and a research plan for trying to find these compositions. The specification contains a description as to what can be done with any compounds that can potentially be identified as COX-2 inhibitors, 5-lipoxygenase inhibitors or immunosuppressive drugs. However, the specification does not disclose which compounds have the desired characteristic for inhibiting COX-2, 5-lipoxygenase or immunosuppressiveness. The instant claims do not disclose structures or identities of compounds that are COX-2 inhibitors, 5-lipoxygenase inhibitors or immunosuppressive drugs all within the same claim. Claims under this rejection either contain no structure disclosure (such as claim 9), or only limited structure (such as claim 10 contains only the 5-lipoxygenase inhibitor) or such as claim 17 contains only a description for the 5-lipoxygenase inhibitor and the Cox-2 inhibitor.

3. Claims 9-20 and 22-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is seen as not enabling for the instant claims because the claims are drawn to a composition containing several active ingredients.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue".

These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims: The claims are drawn to a composition containing any and all known and unknown COX-2 inhibitors, 5-lipoxygenase inhibitors and immunosuppressive drugs.

3) The state of the prior art: The art knows of drugs that are independently COX-2 inhibitors, 5-lipoxygenase inhibitors and immunosuppressive drugs. The art also knows of combinations of two or more of these active ingredients.

5) The level of predictability in the art: With the three-dimensional structures of the enzymes such as COX-2, it is not within the skill of the ordinary artisan to predict what compounds might bind to and inhibit them (University of Rochester v. G.D.Searle & Co. (CAFC 03-1304)).

6) The amount of direction provided by the inventor: The instant specification does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to make or carry out the claimed compositions. One of ordinary skill in the art would have to find a compound, determine what activity it may have, and then put it into a composition with other active ingredients that have yet to be determined

7) The existence of working examples: The art is aware of individual compounds that are either immunosuppressant drugs or COX-2 or 5-lipoxygenase inhibitors. However, the examples are a few currently known compounds compared to the vast number of unknown or undiscovered compounds that potentially exist.


8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The practice of making the claimed compositions would require a person of ordinary skill in the art to engage in undue experimentation, with no assurance of success.

The specification does not provide any guidance with respect to how to make the compounds. The only way to identify the characteristics necessary for recognizing that a compound is a candidate for the instant claims is the activity. That activity must be determined and then the possible compounds must be mixed with other active compounds. The selection of compounds is not enabled by the instant specification. Taking the above into consideration, it is not seen where the instant specification enables the ordinary artisan to make or use the instant invention with any and all COX-2 inhibitor, 5-lipoxygenase inhibitor or an immunosuppressive drugs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 630am-4pm, First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. Margaret Seaman  
Primary Examiner  
Art Unit 1625